Maricopa Integrated Health Systems
Formulary Prior Auth Criteria

Drug: Humatrope (Somatropin)
Saizen
Protropin

Therapy:
Is indicated for the long-term treatment of pediatric patients who have growth failure due to an inadequate secretion of endogenous growth hormone. Other causes of short stature should be excluded

Adult onset:

Patients who have growth hormone deficiency either alone or with multiple hormone deficiencies (hpopituitarism), as a result of pituitary disease, hpothalamic disease, surgery, radiation therapy, or trauma

Inclusions:

A) Request comes from the Endocrinologist

B) Patient failed at least two growth stimulation tests (peak <10 micrograms/ml)

C) For acquired forms of GH deficiency- **Adults Onset**

1) head trauma- transection of pituitary stalk
2) Intracranial lesions- CT or MRI confirmation
3) Irradiation therapy- greater than 2400 rads of cranial radiation
4) Therapy that is associated with abnormal spontaneous generation of growth hormone

D) Children with a diagnosis consistent with GH deficiency

1) Must have proportionate short stature with height <5th percentile on standard growth chart
2) Height and weight of parents
3) Abnormal growth velocity as demonstrated on growth chart (<5cm/year)
    a) Chronic renal failure while awaiting transplantation
    b) Girls with Turner's Syndrome
        a) Chronological age ≥5years
        b) Abnormal growth velocity as demonstrated on growth chart (i.e. <5cm/year)
        c) Endpoint of therapy will be when growth has stopped, (height gain <5cm/year, generally around the chronological age of 12 or 13).
4) Delayed bone age <2 SD from norm as compared with chronological age
5) Absence of chronic disease, psychosocial dwarfism or malnutrition
6) Patient **does not have** a closed or fused epiphyses

Exclusions:

A) High catabolic states
- Burn patients
- Chronic glucocorticoid therapy
- Status post major surgery
- Cardiomyopathy

B) Non-growth hormone deficient short stature
C) Intrauterine growth retardation
D) Downs Syndrome
E) Prader-Willi syndrome
F) Skeletal dysplasias

Additional information:

Discontinuation should be considered

A) Decrease in growth velocity while on rGH therapy, i.e. <5cm/year
B) Bone age of: >14 in females
>16 in males
C) Height attained that is within genetic potential as defined by midparental height:
1) Males

$$\frac{(\text{Mother's height} + 13\text{cm}) + \text{father's height}}{2}$$

2) Females

$$\frac{(\text{Father's height} - 13\text{cm}) + \text{mother height}}{2}$$

D) Poor compliance

Authorization:

Six months
Continue authorization every six months will need

Children:

A) Growth rate of ≥2.5cm/6months
B) Monitored for leukemia, insulin resistance and slipped femoral epiphyses
C) Growth velocity improved since initiation

Adults:

A) Evaluation of patient's serum insulin-like factor I to confirmed appropriateness of current dose
B) Patient improved in any of the following areas: body composition, cardiovascular health, body mineral density, serum cholesterol or physical strength

Medical Director_____
Date_____